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ABSTRACT

Seventy-six hyperactive children (5 to 9 years old) and their families were studied to assess adherence to stimulant medication. Twenty families rejected the offer of treatment. Of those accepting, 20% were no longer taking medication by the fourth month and 44 had ceased by the tenth month. Nonadherence was generally not due to dramatic symptom remission. Several child and parental characteristics were related to adherence. Findings are discussed in relation to the unique nature of using medication to treat behavior problems and the difficulty of carrying out long term studies of the effects of psychopharmacological agents with children. (Author)

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Factors Associated with Children's Adherence to Stimulant Medication

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Seventy-six hyperactive children and their families were studied in order to assess adherence to stimulant medication. Twenty families rejected the offer of treatment. Of those accepting 20% were no longer taking medication by the fourth month and forty-four had ceased by the tenth month. Non-adherence was generally not due to dramatic symptom remission. However, several child and parental characteristics were related to adherence. The findings are discussed in relation to the unique nature of using medication to treat behavior problems in children and the difficulty in carrying out long-term investigations on the effects of psychopharmacological agents with children.

DRUG ADHERENCE

Since hyperactivity is evident in 8-10% of school age children (Barkely, 1979; O'Leary, 1980; Safer and Allen, 1976) and there is ample evidence that many of their problems persist into adolescence and early adulthood (Weiss, Hechtman and Perlman, 1978) it is not surprising that there is considerable interest in the development of effective treatment programs for this population. Presently, stimulant medication is the most widely used treatment for hyperactives (Ross and Ross,1976). In fact, the effects of stimulant medication on hyperactives is the most thoroughly researched treatment in child psychiatry (Gittelman-Klein, Klein; Abikoff, Katz, Gloisten and Kates, 1976). However, several puzzling aspects concerning its effectiveness remain.

Several excellent reviews document the beneficial short term effects of stimulant medication on the classroom and social behavior of hyperactive children (Barkely, 1977, 1979; Cantwell and Carlson, 1978; Whalen and Henker, 1980). However, long term investigations do not support these positive findings (Weiss, Kruger, Danielson and Elman, 1975). Furthermore, there is little evidence, to date, that the academic progress of these children is aided by medication (Barkely, 1979; Barkely and Cunningham, 1978; O'Leary, 1980).

Several suggestions have been made concerning the seeming paradox of enhanced attentional abilities and improved classroom behavior and the lack of accelerated academic gain. It is possible that placing a child on medication does improve attention and behavior but does not compensate for the lack of skills and other variables that predispose a child to academic achievement (Barkely, 1979). Another suggestion is that the demonstrated

lack of academic achievement while taking medication may be due to the insensitivity of the tests to the relatively brief intervention periods utilized in this research (Barkely, 1979; Sprague and Berger, 1980).

A rarely mentioned but nonetheless glaring deficit in the utilization of medication with hyperactives is that of adherence. A survey by Solomons (1973) found that 43% of the children on stimulant medication were not being adequately monitored by a physician. Furthermore, there are virtually no data indicating the percentage of hyperactive children that do not take their prescribed medication appropriately. Briant (1978) suggests that the failure of patients to take medication as prescribed has probably accounted for more variability or lack of consistency in outcome data than any other factor in drug intervention. Investigations with other populations certainly support this claim. It is currently estimated that 50% of adult patients do not take medication as prescribed. Children may fare even worse. Bergman and Werner (1962) studied the compliance rate of children diagnosed as suffering from streptococcal pharyngitis, acute otitis media and skin infections thought to be caused by streptococci. The prescribed treatment consisted of orally ingested penicillin for a ten day period. It was discovered that 56% had stopped taking the medication by the third day, 71% by the sixth and 82% by the ninth day. Similar results were obtained by Mattar, Markello and Yaffe (1975) who found that only 7.3% of 300 pediatric outpatients completed their course of antibiotics for otitis media.

Another serious deficit in the literature on the treatment of hyperactive children is that of subject selection (Firestone and Witt, 1980). There is rarely any mention of the solicitation procedures used or the number of children and families meeting criteria, who for one reason or another reject the offer of treatment. This type of selection bias has been shown to seriously affect the results and limit the generalization of research with schizophrenic adults (Spohn and Fitzpatrick, 1980). As Loney and Halmi (1980) cogently argue, research that does not take exclusion variables into account does not provide much information with which to specify predictors of treatment response. Neither does this type of research allow for a matching of patient variables with the various treatment modalities available.

In order to better understand the problems inherent in the pharmacological treatment of children in general, and hyperactives in particular, this paper will examine the demographic and psychological factors associated with attrition and adherence.

The issue of adherence to drug regimens has been addressed in several recent works (Sackett and Haynes, 1976; Dunbar and Stunkard, 1979;). These reviews pinpoint the strengths and weaknesses of several of the popular methods of assessing adherence such as clinician ratings, pill counts, blood or urine sampling, record keeping and outcome. In the end it is quite clear that one should use a combination of approaches to assess compliance because any simple method has serious handicaps.

The primary goal of the present project was not to increase compliance rates. Rather it was to ascertain what the normal drug usage patterns in an out-patient child population might be. It was therefore felt that the implementation of intrusive monitoring practices might, in fact change these patterns. Therefore adherence was gauged largely through verbal reports from the parents.

METHOD

Subjects

Seventy-six children (8 females) between five and nine years of age referred to the Psychology Department of the Children's Hospital of Eastern Ontario were participants in the investigation. The Hospital is the pediatric center of the region, with a catchment of 600,000 children. The children had as their prime difficulties, over-activity, short attention span, impulsivity, inability to delay gratification and aggressiveness, tantrums or oppositional behaviour (attention deficit disorder with hyperactivity, DSM III). They were required to have a score of 15 or higher on the Hyperactivity Index (HI) of Conners' behaviour rating scale for teachers (TRS; Goyette, Conners, & Ulrich, 1978). Peabody Picture Vocabulary I.Q.s were at least 80 and the children were living at home with at least one parent. The hyperactivity had to be in evidence prior to 2½ years of age and be present at home and at school. Excluded from the sample were children who showed definite signs of brain damage, epilepsy or psychosis. Families in which either parent was psychotic or in which the marital discord was so great that the parents openly admitted intervention would be impossible, were excluded.

PROCEDURE

All children were referred by physicians. Parents and children were then interviewed by a psychologist (P.F.) and each parent was asked to independently fill out Conners' rating scale for parents (Conners, 1970; PRS) a marital satisfaction questionnaire (Locke & Wallace, 1959), and then demographic data were collected. The identified patient's teacher was then contacted and asked to complete the TRS. If the family met the criteria they were randomly assigned to a medication only condition (methylphenidate hydrochloride) or to a group in which parents received instruction in behavior modification techniques while their children received medication (see Firestone, Kelly, Goodman and Davey, 1980, for a description of the parent training). Parents were told their child would be assessed prior to treatment after about 4 months, immediately after the parent training, then approximately every six months after that for three years. If parents agreed to participate, their MMPI and I.Q. data were collected and arrangements for testing the hyperactive child were made. If they rejected treatment, the reasons for this were explored and they were also asked to complete the above measures and tests.

Medication

Medication was provided free of charge for approximately the first four months of the study. After that, patients were required to purchase medication through regular procedures. Parents were instructed to give their children 5 mg. of the medication morning and noon every day including

week ends, until a correct dosage was established. Medication was raised or lowered in 5 mg. gradations, based upon parental and teacher telephone reports, over a 3 to 4 week period. Dosages were determined either by a reported significant decrease in problematic behavior or indications of negative side effects (e.g. headaches, stomach aches, irritability, insomnia). Once the appropriate dosage was established, children generally received medication only on school days. The same person (P.F) was responsible for the titration procedure and for maintaining contact with the parents. All medication changes were carried out in consultation with the referring physicians. The average number of contacts per family by a project person during the first four months was 16 in the parent training condition and 13 in the medication only group. The average dosage of methylphenidate was twenty-two mg. per day with a minimum of 10 mg. and a maximum of 40 mg.

Project personnel attempted at all times to be supportive of the parents' wishes concerning medication use. The parents were informed of medication effects and their child's progress on medication. If however, parents wanted to take their child off medication they were not subjected to any coercion. Rather, they were informed that the project would still like to follow the child's progress in order to advise the parents concerning academic planning and emotional development.

The duration of the investigation was twelve months. Therefore, since most children were kept off medication during the summer vacation, full compliance entailed taking medication for 10 months. Families rejecting

pharmacological intervention or terminating its use prior to the end of the fourth month were classified as non-adherents (N = 32). Adherents were those families who complied with the intervention for nine months or more (N = 26). Seven subjects who took medication from five to 8 months were excluded to ensure independence of the groups.

Rating Scales and Tests

Conners' Rating Scales

Conners (1969) developed a widely used rating scale for teachers. The TRS, a scale of 39 items has been factor analyzed to produce five factors. Only the HI (Goyette, Conners, & Ulrich, 1978) was analyzed in this experiment and the score is based on the total score within the factor (a four point scale, 0-3, is used). This factor has been utilized extensively to assess the effectiveness of psychotropic medication with hyperactive children and has been repeatedly shown sensitive to drug effects (Firestone, Davey, Goodman, & Peters, 1978; Sprague, Christensen & Werry, 1974).

Conners (1970) also developed a rating scale for parents that discriminates between hyperactive, neurotic and normal control children (PRS). This 93 item scale has been factor analyzed to produce eight factors but only the HI was used. It is scored the same way as the TRS.

Assessment of emotional adjustment

Weiss, Kruger, Danielson & Elman (1975) developed this scale to assess the emotional adjustment of hyperactive children in a long-term follow-up of children on methylphenidate or chlorpromazine. This is a three point scale based upon an interview with the parents by a senior psychologist (1, normal; 2, slightly disturbed; 3, severely disturbed). The score is based on the total of seven factors; peer relations, mood, sexual adjustments, relationship with adults, adjustment to authority, number of nervous symptoms and rate of delinquency.

Locke-Wallace Marital Adjustment Test

Locke and Wallace (1959) devised a questionnaire to measure marital adjustment which reliably discriminated between good and poor marriages. The mean adjustment score for the well adjusted group was 135.9 and for the malajusted group, 71.1. Only 17% of the maladjusted group received scores of one hundred or higher, whereas 96% of the well adjusted group achieved scores of 100 or more. This scale has been used extensively in research (Johnson & Lobitz, 1974; Margolin, 1978; Oltmans et al., 1977).

Minnesota Multiphasic Personality Inventory

The MMPI is the most widely used objective test of personality. It allows for a symptomatic self assessment covering a wide range of complaints and fears and in addition, taps a number of areas of distress and allows for a actuarial classification of acknowledged concerns. The test is self administered with the subject answering true or false to a large number of short, structured narrative statements. It is the most widely used personality inventory in research (Butcher & Tellegen 1978).

Shipley Institute of Living Scale

The Shipley Institute of Living Scale was introduced as measure of intellectual performance (Shipley, 1940a, 1940b). It consists of a vocabulary test and an abstract reasoning test and is administered in 20 minutes. The scale has been found to correlate highly with other tests of intellectual functioning.

RESULTS

Seventy-six families met the inclusion criteria and were offered treatment. Of these:

- three children improved so dramatically during the pretests that they no longer required treatment
- nine families rejected any form of treatment
- eleven families declined the offer of treatment if it included stimulant medication, but accepted parent training as an alternative
- ten children responded adversely to methyphenidate and were switched to dextroamphetamine
- eight of these responded adversely to dextroamphetamine and were dropped from the study, while the other two children remained on this medication.

Figure 1 depicts the compliance rates of the families in the two treatment groups. By the fourth month 80% of the children were still taking medication. A chi square analysis did not reveal a differential drop-out rate in the two treatment groups $x^2(1) = .21$, $p > .10$ at the end of the fourth month. By the tenth month, 44% of the children were no longer on medication. Once again, a chi square analysis did not reveal a differential drop-out between groups $x^2(1) = .38$, $p > .10$.

Although there were some minimal side effects in both the adhering and non-adhering groups (lack of appetite at lunch, some difficulty falling asleep), the non-adherents did not report these factors as very important in their decision to stop administering medication. The major reasons given were that parents were not comfortable with the idea of medicating their children and/or the children were reluctant to take their medication. With a few patients in both groups there was some pressure from teachers to take children off medication, despite the fact it seemed to help them. It should be noted that all but three families stopped giving their children medication prior to consulting the project or their physician.

In order to assess whether symptomatic improvement may have lead to the high drop-out rate the HI scores as rated by mothers and teachers, taken as soon as possible after the cessation of medication, were compared to childrens pre-medication scores. Generally, the off-medication ratings were collected within two months of terminating pharmacotherapy. As Table 1 indicates, teachers did, in fact, rate the children as significantly improved compared to when they entered the study. There was a similar trend report by the mothers. However, it is also quite clear that the children were still quite problematic at the time of assessment while off medication. The adherents' most recent scores while still on medication also showed that they improved significantly as rated by both mothers and teachers.

Table 2 reveals that the adherents were rated as significantly more improved while on medication than the non-adherents off medication by teachers. However, the mothers in the two groups did not differ in their ratings of the children.

The characteristics of the children just prior to treatment, in the two compliance groups are presented in Table 3. There was a trend suggesting that non-adherents were younger and scored significantly lower on the intelligence test. No other differences were evident between the groups.

A significant chi square of the sex distribution within the groups was revealed (Table 4). It appears that families were more likely to prematurely discontinue medication if the child was female.

Table 5 presents the characteristics of the families in the compliance groups. Since the literature concerning drop-out in adult psychotherapy indicates that premature terminators tend to have lower IQ's and fewer completed years of schooling (Bergin and Lambert, 1978) and since similiar findings were evident in a study comparing the families of hyperactives that stayed in parent training programs compared with those discontinuing prematurely (Firestone and Witt, 1980) one tailed t-tests were conducted on this data. Mothers and fathers in the non-adherent group were significantly younger than those that complied with the medication regimen. There was also a trend indicating that these parents scored more poorly on intelligence tests. There were no other significant differences between the groups.

There were no significant differences on any of the subscales of the MMPI between the groups.

Discussion

The most clear cut finding in the present study is that a large number of parents cannot or will not use the stimulant medication prescribed for their children. Approximately 26% of the total group refused treatment altogether. Of those agreeing to have their children placed on medication (excluding children who responded with adverse side effects sufficient to preclude continuation on medication) 20% stopped using it by the end of the fourth month. By the end of the tenth month only 55% of the children were still taking their prescribed medication. It is important to note that less than 10% of the families sought consultation prior to terminating pharmacological intervention. Non-adherence was generally discovered when project personnel routinely contacted the families. It is quite likely that less diligent supervision of these families would have led to inflated estimates of compliance rates.

The reasons for terminating medication use in this study are not clear. It does not seem that undesirable side effects or symptom remission were major factors. Although it is clear there was a significant reduction in problematic behaviour in children off medication, as perceived by both mothers and teachers, their behaviour was still seen as quite troublesome. As reported in numerous other studies, the mothers in the adherent and non-adherent groups found their children equally hyperactive. This is not unexpected since the short-lived nature of stimulant medication results in the children being relatively drug free after school and on week-ends.

A significant differential attrition rate by treatment group (parent training plus medication vs medication-only) was not found. However, visual inspection of the data does indicate that parents in the parent training groups may have been slightly more inclined to take their children off medication. It is possible that the larger number of contacts with this group simply evealed non-adherence more accurately. An alternate explanation, based upon parental comments, is that these parents gained a great deal of confidence in their ability to deal with chidren and hence felt they could deal with their child without the use of "drugs".

The findings that younger children, males, children with lower IQ's and younger parents who tend to have lower IQ's are less likely to adhere to medication prescriptions parallels previous work with hyperactives, comparing those who drop out of parent training groups with those that remain (Firestone and Witt, 1980). However, unlike this previous work the personality characteristics of the parents did not predict compliance. Several reviews concerned with adherence of adults to medication regimens support the lack of a personality profile characteristic of non-adherents (Dunbar and Stunkard, 1979; Kasl, 1975; Sackett and Haynes, 1976).

The reasons for and use of stimulant medication with children differ considerably from the manner in which long-term medications are normally administered to adults and may add to non-adherence. Hyperactive children rarely seek assistance for the problems they are experiencing at home or at school. More often than not parents bring a child to a physician for consultation because of the difficulty the child is experiencing at school. However, this difficulty is defined by the school rather than expressed by

the child. Therefore, adults act as the intermediary complainants between the home and/or school and the physician. In fact, the most frequently used diagnostic aids are not the subjective reports of the child but behaviour rating scales filled out by parents and teachers in addition to a developmental history. Neither is the hyperactive child responsible for taking the medication and he or she is only a consultant when it comes to the titration process. Unless the child is suffering from undue side effects, dosages of stimulant medication are raised or lowered based upon adults reports of the child's behaviour. The child is not seen as a reliable reporter of his or her own behaviour. Research into medication usage with adults suggests that such factors all lead to lowered compliance rates (Dunbar and Stunkard, 1979; Kasl, 1975; Sackett and Haynes, 1976).

The behaviour of hyperactives, unlike that of adults, changes over time due to maturation sometimes confounding the changes brought about by medication. Early research with hyperactive children reported they "outgrow" their problems by the time they reach adolescence. Considerable research now exists indicating that although the most evident aspects of the problem such as overactivity may decrease with age, the primary deficits such as attention and impulse control remain (Hoy, Weiss, Minde and Cohen, 1978). Nevertheless, this change in the topography of the problematic behaviour may lead to decreased adherence rates.

Several findings in the present study are quite clear and are of primary importance in relation to research with hyperactive children. The families of a large number of diagnosed hyperactive children do not accept

the pharmacological treatment of their children. This group is rarely mentioned in the research literature. It is not inconceivable that the sometimes contradictory findings concerning the efficacy of stimulant medication is at least partially caused by differential subject selection. Research that does not clearly define exclusion criteria and describe attrition variables and subjects that have dropped out can be as misleading as the inadequate description of the populations that complete drug trials. In addition, it is quite clear that hyperactives are inclined to stop using their prescribed medication. It appears that adherence is inversely related to the time elapsed from the prescription date and that the parents of hyperactives do not normally report their non-adherence to professionals. It is suggested that the seeming paradox of improved abilities, due to stimulant medication, found in short-term studies but not in long-term outcome studies may be partially due to non-adherence to the prescribed medication.

Figure 1. Percentage of Children Adhering to Prescribed Medication

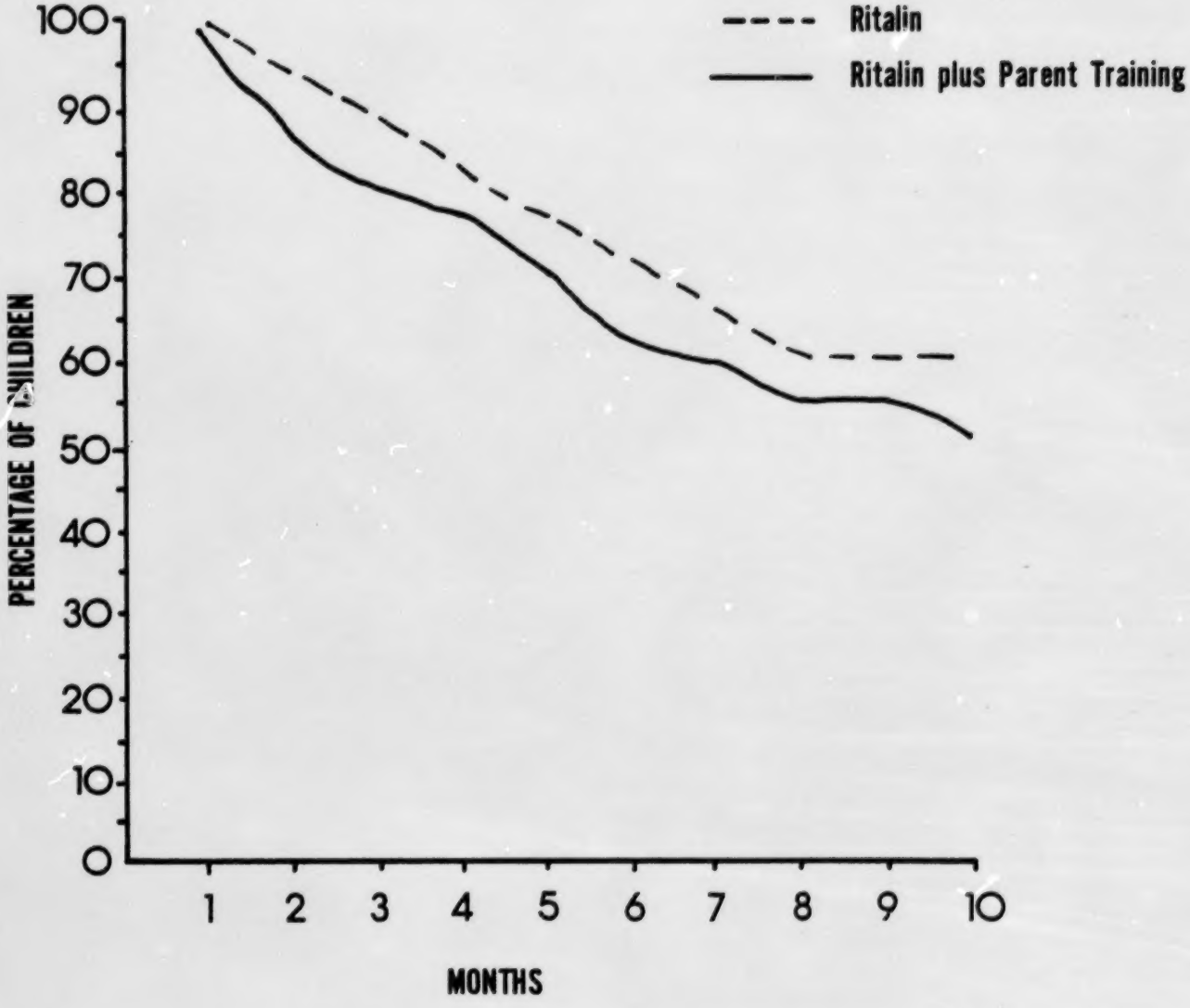

TABLE 1

Mothers' and Teachers' Hyperactivity Ratings

For the Non-Adherents Pre-and Post Medication

Non-Adherents	Pre	Post	t	df	p<
Teachers	20.94 ± 4.22 (17)	14.18 ± 1.77 (17)	3.51	16	.003
Mothers	18.88 ± 4.78	14.00 ± 7.48	1.98	16	.066
Adherents					
Teachers	17.83 + 4.52	7.08 + 3.31	10.19	23	.001
Mothers	22.46 + 5.52	13.00 + 5.24	7.18	23	.001

TABLE 2

Mothers and Teachers Hyperactivity Ratings
for the Adherents and Non-Adherents

	Adherents	Non-Adherents	t	df	p<
Teachers HI	7.08 ± 3.81	14.18 ± 1.77	3.73	22	.001
Mothers HI	13.00 ± 5.24	14.00 ± 7.48	.48	26	NS

TABLE 3

Characteristics of the Children

	Non-Adherents	Adherents	t	df	p<
Age	7.05 ± 1.54 (30)	7.67 ± 1.22 (26)	1.07	54	.10
I.Q.	109.00 ± 15.78 (26)	116.35 ± 13.58 (26)	1.80	49	.04
Mothers' HI	19.82 ± 5.34 (28)	10.84 ± 6.83 (26)	.01	47	-
Teachers' HI	19.41 ± 4.57 (27)	18.77 ± 4.38 (26)	.52	51	-
Emotional Adjustment	12.63 ± 3.48 (16)	12.09 ± 2.76 (23)	.52	27	-

TABLE 4

The Number of Children in Non-Adherent and Adherent Groups

	Non-Adherents	Adherents
Males	24	25
Females	6	1

$\chi^2 (1) = 3.50$ $p < .05$

TABLE 5

Characteristics of the Families

	Non-Adherents	Adherents	t	df	p
Mothers' Age	31.52 ± 3.59 (29)	35.39 ± 6.55 (26)	2.68	38	.01
I.Q.	106.46 ± 9.68 (26)	110.16 ± 9.7 (25)	1.36	49	.09*
Education	12.61 ± 2.41 (28)	12.87 ± 2.48 (26)	.30	51	-*
Marital Satisfaction	104.27 ± 24.13 (22)	108.56 ± 28.61 (25)	.56	45	-
Fathers' Age	33.93 ± 3.78 (27)	33.31 ± 7.71 (26)	2.61	36	.01
I.Q.	104.35 ± 11.39 (23)	110.04 ± 13.05 (25)	1.61	46	.06*
Education	12.37 ± 3.08 (27)	13.12 ± 3.53 (36)	.82	50	-*
Marital Satisfaction	98.64 ± 28.79 (22)	108.67 ± 26.57 (24)	1.22	43	-
Income	23,778 ± 11,171 (27)	26,692 ± 13,102 (26)	.87	49	-
No. of Sibs	1.21 ± 1.32 (29)	1.17 ± .70 (40)	.14		-

* one-tailed t-tests

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